REMARKS

Claims 1-20 are pending in the Subject Application. In the Office Action of June 20, 2008, claims 1-20 stand rejected. Claims 14-15, and 20 have been canceled. New claims 21-23 have been added and find support throughout the specification. Specifically, new claim 21 finds support at page 5, lines 6-10, new claim 22 finds support at page 6, lines 6-11, and new claim 23 finds support at page 5, lines 14-18. Applicant submits that no new matter has been introduced by way of amendment or addition of the new claims. Presently, claims 1-13, 16-19 and 21-23 are pending.

A. Rejection of Claim 21 under 35 U.S.C. § 112, second paragraph

Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Examiner asserts that the phrase "while not impeding permeation of sterilizing gases" is indefinite because the friction enhancing material is applied on the impermeable material and such impermeable material is impermeable to sterilizing gases by definition. The Examiner identifies the rejected claim as claim 21; however, the present application does not currently have claim 21 as part of the record. Instead, Applicant believes that the Examiner intended to reject claim 20 as being indefinite. Claim 20 has been canceled without disclaimer or prejudice. Hence, Applicant respectfully submits that the rejection is obviated and requests that this rejection be withdrawn.

B. Rejection of Claims 1, 2, 6-9, 17 and 19 under 35 U.S.C. § 102(b)

Claims 1, 2, 6-9, 17 and 19 stand rejected under 35 U.S.C. §102(b) as assertedly being anticipated by U.S. Patent No. 5,866,069 to Soto *et al.* (hereinafter "Soto"). Applicant traverses this rejection for the reasons set forth herein.

Claim 1, and claims 2, 6-9, 17 and 19, recite, in part, a sterilization package for enclosing a device during a sterilization procedure and storing the device in sterile form,

wherein at least a portion of an outer surface of the package has friction enhancing material, wherein the friction enhancing material is applied in a pattern while not impeding permeation of sterilizing gases.

The Examiner asserts that Soto teaches each and every element recited in claims 1, 2, 6-9, 17 and 19 of the Subject Application. Applicant respectfully disagrees. Applicant submits that Soto does not teach "friction enhancing material applied in a pattern" as recited in claims 1, 2, 6-9, 17 and 19. Instead, Soto teaches:

> [a]pplication of the silicone can be accomplished by spraying one or both of the opposing sides of a sheet of material utilizing known spraying systems. Silicone can also be applied to the material by exposing the material to an aqueous silicone emulsion comprising silicone or an organic solvent-based system including silicone. (col. 3, lines 52-57)

In addition, Soto teaches:

> [e]xposure to an aqueous emulsion or an organic solvent-based system can be accomplished by a simple dip-and-squeeze process in which the material to be treated is immersed in the aqueous emulsion or the organic solvent-based system. (col. 3, lines 58-62)

Soto also teaches:

> treating a gas-permeable material with a substance including silicone in an amount sufficient to render the material liquid repellent and able to withstand exposure to an oxidizing plasma sterilizing process without losing its repellency. (col. 1, line 66 to col. 2, line 3)

Hence, it is clear that Soto teaches a process where silicone completely covers the sterilized material to make it liquid repellent. Furthermore, Soto teaches that silicone is applied by spraying or immersion in an aqueous emulsion and is not applied in a pattern as recited in claims 1, 2, 6-9, 17 and 19 of the Subject Application.

For a reference to be anticipatory under 35 U.S.C. § 102, it is axiomatic that the reference must teach, either explicitly or inherently, each and every element of the

invention as set forth by the claims. Soto does not teach friction enhancing material applied in a pattern, as recited in claims 1 and 17 and all claims dependent therefrom. For at least this reason, Soto does not anticipate claims 1 and 17 or any of the claims dependent therefrom.

Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 6-9, 17 and 19 under U.S.C. § 102(b) over Soto.

C. Rejection of Claims 1-13 and 16-19 under 35 U.S.C. § 103(a)

Claims 1-13 and 16-19 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Soto in view of The Related Prior Art on pages 1-2 of the Subject Application (hereinafter "The Related Prior Art") or U.S. Patent No. 6,986,730 to Hoekstra *et al.* (hereinafter "Hoekstra"). Applicant respectfully traverses the rejection for at least the reasons as set forth herein.

To determine the obviousness of a claim, an Examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Furthermore, as set forth in MPEP §2142, the key to supporting any rejection under 35 U.S.C. § 103(a) is the clear articulation of the reason why the claimed invention would have been obvious. As the Supreme Court recently stated, "*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

For example, where the Examiner contends that the claimed invention is obvious because of the elements gleaned from the combined teachings of Soto and The Related Prior Art or Hoekstra, the Examiner must explain why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. Applicant respectfully submits, however, that the Examiner has failed to clearly articulate the reasoning in support of the

asserted conclusion of obviousness in view of the combined teachings of Soto and The Related Prior Art or Hoekstra, and that there is no reason why one of ordinary skill in the art would arrive at the sterilization package recited in claims 1 and 17. This is so because there is nothing in Soto or The Related Prior Art or Hoekstra that would teach or suggest friction enhancing material applied in a pattern on the outer surface of a sterilization package, for the reasons as set forth in *Section B*.

In addition, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *See* MPEP §2141.02(VI). In fact, it has been held that an important indicator of non-obvious is "teaching away" from the claimed invention by the prior art or known by those of ordinary skill. *See U.S. v. Adams*, 383 US 39, 148 USPQ 479 (1966). Indeed, express teaching away from the claimed invention is a *per se* demonstration of lack of *prima facie* obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525 (Fed. Cir. 1987).

As discussed above, Soto teaches treating gas-permeable material with a substance including silicone in an amount sufficient to render the material liquid repellent and able to withstand exposure to an oxidizing plasma sterilizing process without losing its repellency (col. 1, lines 66-67 to col. 2, lines 1-3). The material must be completely coated with silicone by spraying or immersion in an aqueous emulsion to make the material liquid repellent. The silicone coating permits sterilization of the material, but not at the same efficiency as non-silicone coated or partially silicone coated material. This conclusion is supported by another reference used by the Examiner in the Office Action, European Publication No. 0863087 to Hoefte (hereinafter "Hoefte"), that teaches, "a package treated with silicone based material is more resistant to outside influences" (page 4, lines 16-18). One of ordinary skill in the art interested in making a package liquid repellent would not apply silicone in a pattern, as recited in claims 1-13 and 16-19 because the pattern will provide more free space and permit the flow of gas more freely and efficiently during sterilization. Indeed, one of ordinary skill in the art reading Soto would be led away from

using friction enhancing material applied in a pattern while not impeding permeation of sterilizing gases, as recited in claims 1 and 17 and the claims that depend therefrom. Instead, one of ordinary skill in the art would be more inclined to completely coat the packaging material with friction enhancing material after reading Soto, thereby preventing the free flow of gas during sterilization.

The Examiner states that "even if Soto teaches coating the entire sheet of material with silicone, it is considered equivalent to a pattern as claimed..." (Office Action, page 6, paragraph 4). Applicant disagrees. Clearly, completely coating the entire sheet of material or package with silicone is not equivalent to applying friction enhancing material in a pattern. If the Examiner's statement was correct, then Hoefte would not have emphasized that silicone treated material is more resistant to outside influences. If the Examiner maintains this line of argument, the Examiner is asked to provide support for the position that silicone applied in a pattern on a package, as recited in independent claims 1 and 17, has a liquid repellency that is equivalent to silicone applied to completely cover a package as taught by Soto.

Furthermore, The Related Prior Art and Hoekstra provide no teaching that cures the deficiencies of Soto. The Related Prior Art teaches a package comprising two film layers with one film formed from TYVEK, which is permeable to sterilization gases and impermeable to potentially contaminating microorganisms. Hoekstra teaches a pouch for packaging medical device comprising a first layer formed from a thermoplastic gas impermeable layer and a second layer formed from TYVEK, which is a gas permeable microbial barrier defined as permeable to sterilizing gases and impermeable to microbial contaminants.

Neither the Related Prior Art nor Hoekstra teach or suggest a sterilization package comprising a friction enhancing material placed in a pattern on the sterilization package while not impeding permeation of sterilizing gases, as recited in claims 1 and 17. Thus, one of ordinary skill in the art, reading Soto and The Related Prior Art or Hoekstra, would not be directed to the sterilization packaging recited in claims 1 and 17 and the claims that depend therefrom.

For the reasons set forth herein, the combined teachings of Soto and The Related Prior Art or Hoekstra do not establish a *prima facie* case for obviousness. Accordingly, Applicant respectfully requests withdrawal of the rejection to claims 1-13 and 16-19 under 35 U.S.C. §103(a) in view of Soto and The Related Prior Art or Hoekstra.

D. Rejection of Claims 1-13 and 16-19 under 35 U.S.C. § 103(a)

Claims 1-13 and 16-19 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over The Related Prior Art or Hoekstra in view of the European Publication No. 0304255 to Katila (hereinafter "Katila"). The Examiner asserts that Katila teaches a package formed from a conventional foil comprising a pattern of friction surface disposed on an outer surface of the package to facilitate stacking of the packages. The Examiner further asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention in view of Katila to modify the package of The Related Prior Art or Hoekstra so at least a portion of the outer surface of the package comprises a friction surface to prevent the package from slipping during stacking with other packages. The Examiner further asserts that the friction enhancing material is applied in a pattern while not impeding permeation of sterilizing gases to allow the package to be sterilized. Applicant respectfully traverses the rejection for at least the reasons as set forth herein.

The Related Prior Art and Hoekstra are clearly distinguishable from the recited claims for at least the reasons set forth in *Section C*. Furthermore, nothing in Katila when combined with these references would render obvious claims 1-13 and 16-19.

As stated in the MPEP §2143.02, "a reasonable expectation of success is required to support a *prima facie* case of obviousness." *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). Applicant contends that one of ordinary skill in the art would not have a reasonable expectation of success of arriving at the claimed invention by combining conventional sterilization packaging, as taught by The Related Prior Art and Hoekstra, with conventional foil sheets, as taught by Katila. One of ordinary skill in the art reading Katila would have no logical reason to use the conventional foil sheets of Katila to wrap the sterilization packages of The Related Prior Art or Hoekstra to promote a frictional

surface. This is so because conventional foil sheets impede permeation of sterilizing gases through the semi-permeable material of the sterilization packaging. Indeed, Katila explicitly teaches the conventional foil sheets are used to wrap packages of perishable products, such as food, fertilizer, and timber (col. 1, lines 47-56). It is respectfully submitted that one of ordinary skill in the art reading Katila would not combine its teachings with that of The Related Prior Art or Hoekstra to provide a sterilization packaging comprising friction enhancing material that is applied in a pattern to enhance friction without impeding the permeation of sterilizing gases, as recited in claims 1-13 and 16-19.

Indeed, Katila can be said to also lead one of ordinary skill in the art away from the invention recited in claims 1-13 and 16-19 because such a modification would result in the destruction of the intended function of the sterilization package; namely to be permeable to sterilizing gases. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed.Cir. 1984).

Thus, a *prima facie* case of obviousness for claims 1-13 and 16-19 in view of the combined teachings of The Related Prior Art or Hoekstra further in view of Katila has not been established. Accordingly, Applicant respectfully requests the withdrawal of the rejection of claims 1-13 and 16-19 under 35 U.S.C. §103(a) in view of The Related Prior Art or Hoekstra further in view of Katila.

E. Rejection of Claims 1-13 and 16-19 under 35 U.S.C. § 103(a)

Claims 1-13 and 16-19 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over The Related Prior Art or Hoekstra in view of Hoefte. Applicant respectfully traverses the rejection for at least the reasons as set forth herein.

Applicant respectfully submits that the combined teachings of The Related Prior Art or Hoekstra in view of Hoefte does not form the basis for an obviousness rejection because one of ordinary skill reading the references would not recognize that the claimed combination of elements would lead to the claimed results. The Related Prior Art and Hoekstra do not teach the use of friction enhancing material and are clearly distinguishable from claims 1-13 and 16-19 for the reasons set forth in *Section C.*

Hoefte provides no teaching that would cure the deficiencies of The Relate Prior Art or Hoekstra. The Examiner states that Hoefte teaches, "a package comprising an outer surface and an anti-slip layer formed from a silicone based material disposed on the outer surface of the package to prevent the package slipping when the package is stacked with other packages (Office Action, page 5). However, Hoefte, at page 4, lines 16-19, teaches:

> [i]t has been further found that the silicone based material according to the present invention is also water repellent. Consequently, a package treated with the silicone based material is more resistant to outside influences, like water and moisture.

Therefore, one of ordinary skill in the art reading Hoefte would understand that a package treated with the silicon based material of Hoefte would also be resistant to outside influences such as sterilizing gases, thus, impeding permeation of sterilizing gases through the semi-permeable material of the sterilization packaging and thereby effect the efficiency of sterilization for the same reasons as set forth in *Section C*. Thus, one of ordinary skill in the art would not combine the teachings of Hoefte with the teachings of The Related Prior Art or Hoekstra, because such a modification would result in the destruction of the intended function of the sterilization package; namely to be permeable to sterilizing gases. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed.Cir. 1984). At the very least, one of ordinary skill in the art would be lead to believe that applying the packaging of Hoefte would impede the permeation of the sterilization gases of sterilization package of the The Related Prior Art or Hoekstra.

Thus, a *prima facie* case of obviousness for claims 1-13 and 16-19 in view of the combination of teachings of The Related Prior Art or Hoekstra further in view of Hoefte has not been established. Accordingly, Applicant respectfully requests the withdrawal of the rejection of claims 1-13 and 16-19 under 35 U.S.C. §103(a) in view of The Related Prior Art or Hoekstra further in view of Hoefte.

F. Rejection of Claims 1-13 and 16-19 under 35 U.S.C. § 103(a)

Claims 1-13 and 16-19 stand rejected under 35 U.S.C. §103(a) as assertedly being

unpatentable over The Related Prior Art or Hoekstra in view of the German Patent No. 1,779,373 to Vollmer (hereinafter "Vollmer"). Applicant respectfully traverses the rejection for at least the reasons as set forth herein.

The Examiner contends that the claimed invention is obvious because of a combination of elements gleaned from the reference teachings. Applicant respectfully submits, however, that there is no reason why one of ordinary skill in the art would make the asserted combination, because there is nothing in any of the references that would lead one of ordinary skill in the art to modify The Related Prior Art or Hoekstra to include the friction enhancing material applied in a pattern on sterilization packaging while not impeding permeation of sterilizing gases.

Claims 1 and 17 and The Related Prior Art or Hoekstra are clearly distinguished for the reasons set forth in *Section C*. Vollmer provides no teaching of semi-permeable sterilization packaging and provides no teaching how the anti-skid coating can be applied to a "sack or bag made of thermoplastic material" in order to arrive at the invention recited in claims 1-13 and 16-19. In particular, claims 1-13 and 16-19 recite a sterilization package comprising friction enhancing material that is applied in a pattern to enhance friction without impeding the permeation of sterilizing gases. Vollmer does not recognize this problem, and provides no solution to address both gas permeability and friction enhancement of a package. Accordingly, one of skill in the art would not be taught to apply Vollmer's teaching to arrive at claims 1-13 and 16-19 of the Subject Application.

Thus, a *prima facie* case of obviousness for claims 1-13 and 16-19 in view of the combination of teachings of The Related Prior Art or Hoekstra further in view of Vollmer has not been established. Accordingly, Applicant respectfully requests the withdrawal of the rejection of claims 1-13 and 16-19 under 35 U.S.C. §103(a) in view of The Related Prior Art or Hoekstra further in view of Vollmer.

G. New Claims 21-23

New claims 21-23 recite a novel and non-obvious sterilization package. None of the cited references, either alone or in combination, teaches or suggests the recited package.

Specifically, none of the cited references teach or suggest, *inter alia*, a sterilization package for enclosing a device during a sterilization procedure and storing the device in sterile form thereafter, the package comprising at least a portion of an outer surface of the package having thereon a friction enhancing material wherein the friction enhancing material is applied on the semi-permeable material in a pattern while not impeding permeation of sterilizing gases and wherein the friction enhancing material is applied on the impermeable material in a pattern while not impairing visibility of the device. Indeed, as set forth in the present specification, it is an advantage to apply the friction enhancing material to the sterilization package in a pattern on the semi-permeable material while not impeding permeation of sterilizing gases and in a pattern on the impermeable material while not impairing visibility of the device (page 5, lines 6-10). None of the cited references teach or suggest this package or these benefits.

In addition, none of the cited references teach or suggest, *inter alia*, a sterilization package wherein the silicone is selected from a group consisting of polydimethyl siloxane, polydiphenylmethyl siloxane and derivatives thereof.

Furthermore, none of the cited references teach or suggest, *inter alia*, a sterilization package wherein the friction enhancing material has a static coefficient of at least 0.2.

Thus, Applicant believes that claims 21-23 are patentable in view of the cited prior art. Accordingly, consideration and allowance of new claims 21-23 is respectfully requested.

CONCLUSION

For at least the reasons discussed above, Applicant respectfully requests reconsideration of the rejections of claims 1-13 and 16-19 and allowance of all claims 1-13, 16-19 and 21-23. Applicant respectfully submits that the present claims are clearly distinguished over the prior art of record and are in proper form for allowance.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below. Applicant submits that if any additional fee is necessary for consideration of this Response, the Commissioner is hereby authorized to charge the additional required fees to Account No. 11-1110.

Respectfully submitted,

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